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10/682,011

10/09/2003

Murtaza F. Alibhai

38-21(51842)C

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04/21/2005

MONSANTO COMPANY

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ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)

ST. LOUIS, MO 63167

EXAMINER

SAIDHA, TEKCHAND

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/682,011

Applicant(s)

ALIBHAI ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.
2. The Preliminary Amendment filed October 9, 2003 is acknowledged. Claims 1-7 & 11-12 have been cancelled. Claims 8-10 are pending.

3. ***Election/Restriction***

Applicants were subjected to a restriction requirement in the parent application 09/755,274, filed January 5, 2001, now US Patent 6,657,046. In this divisional application, Applicants elect Group III, claims 8-10, species SEQ ID NO: 21, drawn to a method of protecting a plant from Coleopteran insect infestation, with traverse.

Applicants argue that the Examiner believes that the sequences as disclosed are not capable of use together, and that each has a different function and/or effect. However, the specification clearly sets out that these sequences as disclosed are capable of use together (specification page 38, lines 14-16) and that the sequences do not have different function and/or effect (specification page 38, lines 20-29).

Applicants' arguments were considered and not found persuasive because the instant specification on page 38, lines 14-16, reveals that the 'Patatins (or the family of insect inhibitory proteins) afford different gene products for control of insect pests with different mode of action. There is further no evidence that all the various proteins listed in claims 8 [SEQ ID NO: 14, 15 & 42, the conserved motifs] or claim 9, are involved in the control 'coleopteran insect infestation' as claimed. Patatin is a mixture of at least 6 to 10 closely related polypeptides, isoforms, or isozymes which differ in their primary amino acid sequence, patterns of glycosylation and hydrolytic activities (Hofgren et al., Plant Sci. 66:221-230, 1990) [see instant specification, page 23,

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lines 7-10]. Therefore, the various protein sequences are distinct structurally and in the level of activities, and perhaps vary or are specific in their mode of action for controlling a particular kind of insect, rather than any insect. Therefore, the restriction requirement made in the parent is still deemed proper and is therefore made FINAL.

4. Claims 8-10 are pending and being examined with respect to the elected sequence of SEQ ID NO: 21. Method claims pertaining to other sequences are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed.

5. **Priority**

Applicant's claim for domestic priority under 35 U.S.C. 119(e), filed 01/06 & 07/21/2000, is acknowledged.

6. **Sequence Rules**

The instant specification, for example, on page 9, lines 13 & 14, & on page 38, lines 22-23, present amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of four or more residues or 10 or more nucleotides must be identified by a SEQ ID NO: ?. The amino acid sequences presented do not have SEQ ID NO: . In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NO: ?, and where required provide a new version of the sequence listing and Computer readable form (disk), both the paper copy and the CRF being identical.

In case the sequences are already listed in the paper copy of the submitted 'Sequence Listing', the specification may be amended to insert the SEQ ID Nos. Applicants' cooperation is requested in checking the entire specification for missing SEQ ID Nos., followed by appropriate amendments.

7. **Specification**

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The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. ***Claim Objections***

Claim 9 is objected to because of the following informalities: Claim 9 recites non-elected SEQ ID Nos. which are to be deleted. Appropriate correction is required.

9. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a plant from coleopteran insect infestation by transforming the said plant with a DNA encoding a protein of SEQ ID NO: 21 having insect inhibitory and lipid acyl hydrolase activities, does not reasonably provide enablement for a method of protecting a plant from coleopteran insect infestation by providing to the plant any protein comprising the motifs of SEQ ID Nos. 14, 15 & 42 or the protein of SEQ ID NO: 21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of

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direction or guidance presented, and the amount of experimentation necessary].

The claims are drawn to encompass a method of protecting a plant from coleopteran insect infestation by providing any protein comprising the motifs of SEQ ID Nos. 14, 15 & 42 or the protein of SEQ ID NO: 21. The specification, however, only discloses the full length DNA sequence of the encoding protein of SEQ ID NO: 21. Barring a single 'insect bioefficacy assay', wherein SCRW larvae are feed on a diet containing the inhibitory protein and evaluated for mortality and growth stunting. Applicants' data in Table 4 (page 56) demonstrate reduction in growth of the larvae as result of the ingestion of the inhibitory protein. However, no mortality data is presented.

The specification is devoid of specific working examples, amount of direction or guidance pertaining to – (1) the method of application of the 'inhibitory protein' or SEQ ID NO: 21 to the plant (how is the protein provided to the plants ?), is it sprayed on the plants ?, (2) what is effective amount and concentration of the protein (dosage) that can protect the plant against the 'coleopteran insects', (3) if externally applied how is the 'protein' effective without being degraded or losing its activity ?, (4) how are the various permutations and combinations (variants) of the protein encompassing the motifs of SEQ ID Nos. 14, 15 & 42 prepared, (5) as inadequate guidance is provided to one skilled in the art to practice the entire breadth of the claimed invention.

Claim 8 is so broad as to encompass a method of protecting a plant from coleopteran insect infestation by providing a protein having 'coleopteran insect inhibitory & hydrolase activities' (referred now on as 'dual or bi-functional'), wherein the protein comprises the motifs of SEQ ID Nos: 14, 15 & 42, wherein each of the selected motifs is modified by varying the amino acids. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number of bi-functionally active proteins

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broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of SEQ ID NO: 21. While, the motifs of SEQ ID Nos: 14, 15 & 42 are taught to be the conserved motifs of the protein in question, the instant specification or the state of the prior art does not teach or show how these motifs or the modified motifs are associated with the inhibitory or hydrolase activities.

The specification does not support the broad scope of the claims which encompass all modifications of any protein having the dual or bi-functional activities comprising the motifs of SEQ ID Nos: 14, 15 & 42 and modifications thereof, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting bi-functional activity; (B) the general tolerance of bi-functional protein to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any bi-functional protein residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of effectiveness or applicability of the method and the preparation of the bi-functional protein having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue in

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using the modified enzyme in the method claimed. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

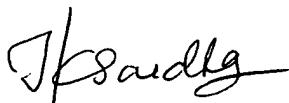
10. In parent case 09/755,274, now USP 6,657,046, the claims are drawn to the polypeptide of SEQ ID NO: 21, & is cited here for reference.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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